K083649

Appendix 2: 510(k) Summary

MAR 9 2009

A. Sponsor

Digirad Corporation
13950 Stowe Drive
Poway, California 92064
Contact Person: Joel Tuckey
Tel: (858) 726-1527
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B. Date Prepared: December 8, 2008

C. Device Name

Trade Name:	Cardius 3 X-ACT Imaging System
Common Name:	Gamma Camera System
Classification Name:	System, Emission Tomography
Device Class:	21CFR 892.1200, Class II
Product Code:	KPS

D. Cleared/Predicate Devices

The Cardius 3 X-ACT Imaging System is substantially equivalent to the following cleared devices:

(1) BrightView VCT Imaging System cleared April 11, 2008 under K080927 for Philips Medical Systems

(2) Cardius 3 XPO Imaging System cleared March 23, 2007 under K070542, and September 12, 2008 under K082368 for Digirad Corporation.

E. Device Description

The Cardius® 3 X-ACT Imaging system is a gamma camera for the acquisition and processing of Single Photon Emission Computed Tomography (SPECT) as well as correcting attenuation artifacts associated with these Emission studies. The device consists of an x-ray generator integrated with the previously cleared Cardius 3 XPO triple head SPECT system to provide attenuation correction functionality. The attenuation correction functionality will be included with the Cardius 3 X-ACT imaging system, or offered as an accessory for previously purchased Cardius 3 XPO systems that are configured to accept the attenuation correction functionality.

The Cardius 3 X-ACT Imaging system is designed to provide extended imaging functionality relative to the current Cardius XPO series imagers. A typical patient study comprises an emission (SPECT) study followed by a transmission study. The SPECT study is acquired using the similar system hardware and software technology as a Cardius-3 XPO imaging system. For the transmission study, the low dose x-ray generator is used to produce an attenuation map that is used for attenuation correction (AC) of the emission data. An iterative reconstruction technique then uses the attenuation map and the SPECT data as input, and the

AC and non-AC reconstructed volumes are saved in the database for physician review. The attenuation correction data provided is additional information that may be reviewed by the interpreter. The original SPECT data remains available to the interpreter.

F. Intended Use

The intended use is the same as the predicate devices. The Cardius 3 X-ACT Imaging System is a gamma camera for Single Photon Emission Computed Tomography (SPECT) integrated with an attenuation device consisting of an x-ray generator. Cardius 3 X-ACT produces non-attenuation corrected SPECT Images and attenuation corrected SPECT images with x-ray transmission data that may also be corrected for scatter.

G. Technology

The Philips Medical Systems BrightView VCT imaging system (K080927) and Digirad's Cardius 3 XPO (K070542 and K082368) predicate devices have similar technology (gamma camera for SPECT imaging and x-ray based attenuation correction), and the same intended use as the Cardius 3 X-ACT imaging system. In Cardius 3 X-ACT, Digirad's internally developed proprietary algorithms are implemented using software technology. A low-dose x-ray generator is used for attenuation correction. Digirad's solid state detectors are used to acquire both emission (SPECT) and transmission scans. The transmission and emission scans share the same imaging plane. The patient sits upright in a chair that rotates to acquire both emission and transmission scans.

H. Testing

Verification and Validation tests were conducted to demonstrate the Cardius 3 X-ACT functioned as per its specifications. Bench testing was done per guidelines for radiation measurements. All tests passed with the actual results substantially matching the expected results. The testing shows Cardius 3 X-ACT meets the design specifications, which are similar to the predicate device functional specifications. Digirad internal testing and clinical images obtained with the Cardius 3 X-ACT imaging system have demonstrated equivalent efficacy to the predicate devices, and did not raise new questions regarding safety and effectiveness.

I. Conclusion

Testing results demonstrate that the Cardius 3 XPO Imaging System meets the specifications and is substantially equivalent to the predicate devices, based on comparisons of intended use and technology, and overall system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 2009

Mr. Joel Tuckey
Vice President Quality
Digirad® Corporation
13950 Stowe Drive
POWAY CA 92064-8803

Re: K083649
Trade/Device Name: Cardius 3 X-ACT Imaging System
Regulation Number: 21 CFR §892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: March 3, 2009
Received: March 4, 2009

Dear Mr. Tuckey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use
510(k) Number (if known): K083649
Device Name:
Cardius 3 X-ACT Imaging System

Indications for Use:

The Cardius 3 X-ACT Imaging System is a gamma camera for Single Photon Emission Computed Tomography (SPECT) integrated with an attenuation device consisting of an x-ray generator. The Cardius 3 X-ACT Imaging System is intended for use in the generation of cardiac studies, including planar and SPECT studies, in nuclear medicine applications. Cardius 3 X-ACT produces non-attenuation corrected SPECT Images and attenuation corrected SPECT images with x-ray transmission data that may also be corrected for scatter.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)
AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083649